IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

JAN VALLEJO, Individually and as Personal Representative of Steve Vallejo, **Plaintiff,** **vs.** **AMGEN, INC., WYETH, INC., and PFIZER, INC.,** **Defendants.**	**CASE NO. 8:14CV50** **MEMORANDUM AND ORDER**

This matter is before the Court on the Motion to Dismiss (Filing No. 10) submitted by Defendants Amgen, Inc., Wyeth, Inc., and Pfizer, Inc. (collectively "Defendants"). For the reasons that follow, the motion will be granted in part and Plaintiff will be given leave to amend.

FACTS

For purposes of the pending motion, all well-pled facts in the Plaintiff's Complaint (Filing No. 1) are accepted as true, though the Court need not accept Plaintiff's conclusions of law. The following is a summary of the factual allegations.

This is a diversity[1] case arising out of the use of Enbrel® ("Enbrel") by Steve Vallejo ("Decedent") to treat his rheumatoid arthritis. Jan Vallejo, individually and as personal representative of Decedent's estate ("Plaintiff"), alleges that Decedent died as a result of his use of Enbrel. Decedent began using the medication in or about 2004,

[1] Jan Vallejo, and Steve Vallejo's estate, are citizens of Nebraska for purposes of diversity jurisdiction. Amgen, Inc. is a citizen of Delaware and California. Wyeth, Inc. is a citizen of Delaware and New Jersey. Pfizer, Inc. is a citizen of Delaware and New York.

and later experienced complications from myelodysplastic syndrome, leading to his death on May 21, 2011.

Enbrel was approved by the U.S. Food and Drug Administration ("FDA") in May 1999 as a biopharmaceutical treatment for autoimmune diseases. It also was used in the treatment rheumatoid arthritis. At all relevant times, Defendants were engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling Enbrel in interstate commerce, either directly or indirectly, through third parties or related entities.

Decedent and his prescribing health care providers were unaware of the full nature and degree of increased risks associated with the use of Enbrel. If the health care providers had been aware of such risks, they would have prescribed other treatments for Decedent's rheumatoid arthritis and/or taken other steps to manage the risks associated with his use of Enbrel. Since at least 2004, Enbrel's labels mentioned the risk of "hematological events." Before Decedent suffered his Enbrel-related injuries, however, doctors and patients were not warned that Enbrel could cause myelodysplastic syndrome.

As a direct and proximate result of Decedent's use of Enbrel, he and his estate suffered noneconomic and economic damages, and Plaintiff in her individual capacity as Decedent's surviving spouse also suffered damages.

STANDARD OF REVIEW

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "[A]lthough a complaint need not include detailed factual allegations, 'a plaintiff's obligation to provide the grounds of

his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" *C.N. v. Willmar Pub. Sch., Indep. Sch. Dist. No. 347*, 591 F.3d 624, 629-30 (8th Cir. 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "Instead, the complaint must set forth 'enough facts to state a claim to relief that is plausible on its face.'" *Id*. at 630 (citing *Twombly*, 550 U.S. at 570).

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ritchie v. St. Louis Jewish Light*, 630 F.3d 713, 716 (8th Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (internal quotation marks omitted). "Courts must accept . . . specific factual allegations as true but are not required to accept . . . legal conclusions." *Outdoor Cent., Inc. v. GreatLodge.com, Inc.*, 643 F.3d 1115, 1120 (8th Cir. 2011) (quoting *Brown v. Medtronic, Inc.*, 628 F.3d 451, 459 (8th Cir. 2010)) (internal quotation marks omitted). "A pleading that merely pleads 'labels and conclusions,' or a 'formulaic recitation' of the elements of a cause of action, or 'naked assertions' devoid of factual enhancement will not suffice." *Hamilton v. Palm*, 621 F.3d 816, 817-18 (8th Cir. 2010) (quoting *Iqbal*, 556 U.S. at 678). The complaint's factual allegations must be "sufficient 'to raise a right to relief above the speculative level.'" *Williams v. Hobbs*, 658 F.3d 842, 848 (8th Cir. 2011) (quoting *Parkhurst v. Tabor*, 569 F.3d 861, 865 (8th Cir. 2009)).

When ruling on a defendant's motion to dismiss, a judge must rule "on the assumption that all the allegations in the complaint are true," and "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is

improbable, and 'that a recovery is very remote and unlikely.'" *Twombly*, 550 U.S. at 555 & 556 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). The complaint, however, must still "include sufficient factual allegations to provide the grounds on which the claim rests." *Drobnak v. Andersen Corp.*, 561 F.3d 778, 783 (8th Cir. 2009).

"Two working principles underlie . . . *Twombly*. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id*. at 679 (citing *Twombly*, 550 U.S. at 556). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*.

DISCUSSION

I. Plaintiffs' Claims based on Strict Liability Failure to Warn and Negligent Failure to Warn

Defendants argue that Plaintiff's claims based on strict liability failure to warn and negligent failure to warn (Counts II and IV) should be dismissed because they are barred by the learned intermediary doctrine. Defendants also argue that these claims are preempted by federal law to the extent that they allege fraud on the FDA, and that the negligence claim should be dismissed to the extent it is based on a post-sale duty to warn.

A. Learned Intermediary Doctrine

In Nebraska,[2] "[a] manufacturer or other seller is subject to liability for failing either to warn or adequately to warn about a risk or hazard inherent in the way a product is designed that is related to the intended uses as well as the reasonably foreseeable uses that may be made of the products it sells." *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 841 (Neb. 2000) (quoting *Rahmig v. Mosley Mach. Co.*, 412 N.W.2d 56, 72 (Neb. 1987)) (internal marks omitted). Ordinarily, a manufacturer's duty to warn runs directly to consumers. *Id.* at 841. Because a patient's prescribing or treating physician is usually in the best position to determine whether a patient should use a pharmaceutical product, however, such products are generally treated differently with regard to the duty to warn. *Id.* at 841-42. In such cases, Nebraska courts generally apply the learned intermediary doctrine. *Id.* at 842. When the learned intermediary doctrine applies, a defendant's duty to warn is discharged if the defendant provided adequate warnings to a patient's prescribing health-care provider. *Id.* Where the doctrine applies, a plaintiff's claims are only barred under the doctrine if the Court finds, as a matter of law, that adequate warnings were given to the plaintiff's health care provider. *See, e.g., Wendell v. Johnson & Johnson*, C 09-04124 CW, 2010 WL 271423 (N.D. Cal. Jan. 20, 2010). ("A claim is not barred by the learned intermediary doctrine when the adequacy of the manufacturer's warning to physicians is at issue.").

[2] The parties do not dispute that Nebraska law applies in this case.

Here, the parties disagree about whether the warnings provided to Decedent's physicians were adequate as a matter of law and whether any exceptions to the learned intermediary doctrine apply.

The Nebraska Supreme Court has not addressed the adequacy of specific warnings in the context of pharmaceutical products. For this reason, the Court looks to the law of other jurisdictions on the subject,[3] recognizing that the test is one of "reasonableness." *See Freeman*, 618 N.W.2d at 841; *Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986) *aff'd*, 758 P.2d 206 (Kan. 1988) *overruled on other grounds by Bd. of Cnty. Comm'rs of Sedgwick Cnty. v. City of Park City*, 260 P.3d 387 (Kan. 2011) ("In determining warning issues, the test is reasonableness.") In other jurisdictions, "[t]o find a warning adequate as a matter of law, the label must 'accurately and unambiguously convey the scope and nature of the risk, with sufficient specificity given the particular . . . risk at issue.'" *Rowland v. Novartis Pharm. Corp.*, 2:12-CV-01474, 2014 WL 3735622, at *12 (W.D. Pa. July 28, 2014) (quoting *In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 817 F. Supp. 2d 535, 546 (E.D. Pa. 2011); *see also Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 105 (Fla. 1989) ("While in many instances the adequacy of warnings concerning drugs is a question of fact, . . . it can become a question of law where the warning is accurate, clear, and unambiguous.") "In the prescription drug arena, expert medical testimony is generally required 'to determine

[3] In determining the law of Nebraska, this Court is "bound by the decisions of the Nebraska Supreme Court." *Anderson v. Nissan Motor Co.*, 139 F.3d 599, 601 (8th Cir. 1998) (internal marks omitted). Where the Nebraska Supreme Court has not addressed the issue before the Court, the Court "must determine what the [Nebraska Supreme Court] would probably hold were it to decide the issue. In making this determination, we may consider relevant state precedent, analogous decisions, considered dicta, scholarly works and any other reliable data." *Id.* at 601-02 (internal marks omitted).

whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect.'" *Rowland*, 2014 WL 3735622, at *12 (quoting *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa. Super. 1996).) "Facially accurate statements of fact regarding a particular risk are not adequate as a matter of law where there are disputes over whether the warning was sufficiently explicit and detailed." *Id.*; *see also Small v. Amgen*, Inc., 2:12-cv-476, 2014 WL 897033, at *5 (M.D.Fla. March 6, 2014) (declining to grant motion to dismiss where the warning label for Enbrel contained a general warning of infection and warnings regarding specific types of infections, but did not provide a specific warning of the type of infection the plaintiff suffered).

It is undisputed that since at least 2004 the labeling for Enbrel provided a warning of the risk of hematological events. Plaintiff does not dispute that myelodysplastic syndrome is a hematological event. Defendants admit that the labeling for Enbrel did not specifically mention myelodysplastic syndrome. At this stage of the proceedings, the Court cannot determine whether a broad warning of hematological events is adequate as a matter of law to warn of myelodysplastic syndrome. Accordingly, the Court cannot conclude as a matter of law that the learned intermediary doctrine applies to bar Plaintiff's claim, and so the Court will not address the question of whether exceptions to the doctrine may be applicable.

B. Federal Preemption

Defendants argue that Plaintiff's claims based on strict liability and negligent failure to warn are impliedly preempted insofar as the claims allege fraud on the FDA. Plaintiff asserts that she is *not* alleging fraud on the FDA. She contends that the

Defendants failed to provide information to the FDA, and such is evidence of their *negligence*. Because Plaintiff represents that she is not alleging that the Defendants committed a fraud on the FDA, the Court need not address Defendants' federal preemption defense at this juncture.

C. Post-Sale Duty to Warn

To the extent Plaintiff's claims based on strict liability and negligent failure to warn allege post-sale duties, Defendants contend that the claims are barred under Nebraska law. Defendants refer the Court to *Anderson v. Nissan Motor Co.*, 139 F.3d 599, 602 (8th Cir. 1998), in which the Court of Appeals concluded that general Nebraska products liability law suggests the Nebraska Supreme Court would *not* impose a post-sale duty-to-warn on product manufacturers. Plaintiff did not respond to this argument in her brief. In light of *Anderson*, Plaintiff's claims based on strict liability and negligent failure to warn are barred to the extent that they allege post-sale duties to warn.

II. Plaintiff's Claim based on "Fraud"

Count VII[4] in Plaintiff's Complaint (Filing No. 1) is labeled "Fraud." (*Id.* at ECF 20.) The substance of Count VII is as follows:

> 100. Defendants, and each of them, engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts with the intent that others rely unpin [sic] such concealment suppression or omission. Such omissions are detailed above.

[4] The counts in Plaintiff's Complaint are incorrectly numbered. The Complaint contains seven claims for relief; however, it does not contain a claim labeled "Count V" and contains two claims labeled "Count VII." For purposes of this Memorandum and Order, when the Court refers to Count VII, the Court is referencing Plaintiff's claim in Filing No. 1, pages 20 and 21, entitled "Fraud."

> 101. Such unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts constitute conduct in violation of the Nebraska Unfair Trade Practices Act, NE Rev. Statue 87-302 *et seq*.
>
> 102. As a direct and proximate result of one or more of these wrongful acts or omissions of the defendants, and each of them, Plaintiff suffered damages recoverable and/or compensable under the aforementioned statutes.
>
> 103. Plaintiffs suffered an ascertainable loss of money or property as a result of Defendants' use of employment of unconscionable commercial practices a set forth above, and seek treble damages, attorney's fees and costs of suit.
>
> 104. WHEREFORE Plaintiffs demands [sic] judgment against defendants individually, jointly, severally and in the alternative damages in an amount greater than $75,000 as well as punitive damages together plus interest, costs of suit and attorneys' fees and such other relief as the Court deems equitable and just.

(*Id.* at ECF 20-21.) Defendants move to dismiss Count VII on three grounds: (1) failure to state a claim under Fed. R. Civ. P. 9(b), (2) failure to state a claim under the Nebraska Unfair Trade Practices Act, and (3) judicial estoppel.

A. Fed. R. Civ. P. 9(b)

In her brief, Plaintiff admits that Count VII is not a fraud claim. She explains that this cause of action was incorrectly titled and should have been titled "Unfair Business Practices." (Filing No. 17 at 9-10.) Because Plaintiff concedes that Count VII is not a claim alleging fraud, the Court need not address Defendants' arguments pursuant to Fed. R. Civ. P. 9(b). To the extent that Count VII presents a claim based on fraud, Defendants' motion to dismiss will be granted.

B. Nebraska Consumer Protection Act and Nebraska Unfair Trade Practices Act

Plaintiff states that Count VII is based on violations of the Nebraska Uniform Deceptive Trade Practices Act, Neb.Rev.Stat. § 87-301 *et seq.* ("UDTPA") and/or authorized under the Nebraska Consumer Protections Act, Neb.Rev.Stat. §§ 59-1601 *et seq*. ("NCPA").

For the following reasons, Plaintiff's claims for relief under the UDTPA and/or the NCPA do not set forth "enough facts to state a claim to relief that is plausible on its face." *Willmar Pub. Sch., Indep. Sch. Dist. No. 347*, 591 F.3d at 630 (quoting *Twombly*, 550 U.S. at 570) (internal quotation marks omitted).

UDTPA

The UDTPA prohibits a broad range of deceptive trade practices. *Triple 7, Inc. v. Intervet, Inc.*, 338 F. Supp. 2d 1082, 1087 (D. Neb. 2004) (citing Neb.Rev.Stat. § 87–301 *et seq*.). "However, it does not provide a private right of action for damages." *Id*. (citing Neb.Rev.Stat. § 87–303).

Plaintiff has not sought injunctive relief, but suggests her prayer for "such other relief as the Court deems equitable and just" (Filing No. 1 ¶ 104) saves her claim under the UDTPA. Her general prayer leaves the Court to speculate as to what equitable relief, if any, Plaintiff seeks; and she does not include any factual allegations supporting her entitlement to such relief. Accordingly, she has failed to state a plausible claim for relief under the UDTPA.

NCPA

To the extent that Count VII is a claim for damages under the NCPA, Plaintiff also has failed to state a claim upon which relief can be granted. She has not identified

any conduct on the part of the Defendants that violated the NCPA. Instead, Count VII merely alleges that Defendants' "conduct [violated] the Nebraska Trade Practices Act, NE Rev. Statue 87-302 *et seq*." (Filing No. 1 at 20.) Count VII gives no notice to Defendants that any claim is made under the NCPA, and it does not state a plausible claim for relief under the NCPA.

C. Judicial Estoppel

Defendants argue that Count VII is barred by the doctrine of judicial estoppel regardless of whether it is a claim for fraud, a claim under the UDTPA, or a claim under the NCPA. "The doctrine of judicial estoppel 'protects the integrity of the judicial process.' A court invokes judicial estoppel when a party abuses the judicial forum or process by making a knowing misrepresentation to the court or perpetrating a fraud on the court." *Stallings v. Hussmann Corp*., 447 F.3d 1041, 1047 (8th Cir. 2006) (quoting *Total Petroleum, Inc. v. Davis*, 822 F.2d 734, 738 n. 6 (8th Cir.1987)) (internal citations omitted). A court considers several factors in deciding whether to apply judicial estoppel:

> First, a party's later position must be "clearly inconsistent" with its earlier position. Second, courts regularly inquire whether the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create "the perception that either the first or the second court was misled[.] Absent success in a prior proceeding, a party's later inconsistent position introduces no "risk of inconsistent court determinations," and thus poses little threat to judicial integrity. A third consideration is whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped.

New Hampshire v. Maine, 532 U.S. 742, 750-51 (2001). These factors are not an exhaustive list and "additional considerations may inform the doctrine's application in specific factual contexts." *Id.* at 751.

To follow Defendants' argument regarding judicial estoppel, the Court will provide a procedural history of this action. Plaintiff originally filed an action against Defendants in the Ventura County Court in California ("California Action"). (Filing No. 17 at 8.) Defendants removed the California Action to the United States District Court for the Central District of California. (*Id.*) Later, the United States District Court for the Central District of California granted Plaintiff's motion to remand. Thereafter, Defendants filed a motion to dismiss on *forum non conveniens* grounds. (*Id.* at 9.) Plaintiff opposed the motion to dismiss. On November 13, 2013, the Ventura County Court issued an order conditionally granting Defendants' motion to dismiss. (Order Granting Defendants' Motion to Dismiss on the Ground of *Forum Non Conveniens* ("Ventura Order"), Filing No. 12 at ECF 39-42.) The order granting dismissal included the following language:

> IT IS HEREBY ORDERED that the [California Action] be, and hereby is dismissed, pursuant to the following conditions:
>
> PROVIDED that within ninety days of [November 13, 2013] Plaintiff re-files her action asserting the same or fewer causes of action asserted in this Action against the same or fewer of the defendants named in this Action in a federal court in Nebraska,
>
> 1. Defendants agree not to assert in a court located in Nebraska any defense based upon lack of jurisdiction;
>
> 2. Defendants agree to toll the statute of limitations from May 17, 2013, the date of filing of the complaint in this Action through the date of the filing of a new action in a federal or state court in Nebraska; and

3. Defendant Amgen agrees to produce in Nebraska any witnesses the court deems necessary for trial, but reserves the right to move *in limine* to exclude any witness.

4. Defense to pay plaintiff federal court filing fee in Nebraska.

(*Id.* at ECF 40.)

Defendants argue that judicial estoppel bars Plaintiff from pursuing Count VII because the Ventura Order limited her to "asserting the same or fewer causes of action asserted in [the California Action] against the same or fewer of the defendants named in [the California Action] in a federal court in Nebraska . . . ." (*id.*); the county court provided a tentative ruling on Defendants' motion to dismiss; and Plaintiff's counsel agreed to the language of a proposed order. (Filing No. 19 at ECF 11.) Plaintiff admits that she did not plead a claim for fraud[5] in the California complaint, but maintains that she never agreed to waive the right to bring a new cause of action against the Defendants.

Applying the *New Hampshire* factors, the doctrine of judicial estoppel does not bar the Plaintiff from pursuing Count VII. Because Count VII is a new count not asserted in the California Action, however, the Defendants are not bound by the restrictions set out in the Ventura Order.

III. Plaintiff's Claims based on Strict Liability for Defective Design

In Nebraska, to recover in strict liability for a design defect, a plaintiff must show:

(1) the defendant placed the product on the market for use and knew, or in the exercise of reasonable care should have known, that the product

[5] Plaintiffs' complaint in the California Action does not include a claim for fraud or a claim entitled unfair business practices. However, Plaintiffs deny that Count VII constitutes a new cause of action. Plaintiffs argue that it is sufficient that they pled the underlying facts supporting Count VII in the California Action.

> would be used without inspection for defects; (2) the product was in a defective condition when it was placed on the market and left the defendant's possession; (3) the defect is the proximate or a proximately contributing cause of the plaintiff's injury sustained while the product was being used in a way and for the general purpose for which it was designed and intended; (4) the defect, if existent, rendered the product unreasonably dangerous and unsafe for its intended use; and (5) the plaintiff's damages were a direct and proximate result of the alleged defect.

Jay v. Moog Automotive, Inc., 652 N.W.2d 872, 880-81 (Neb. 2002). With regard to element four, Plaintiff is required to plead that the Enbrel Decedent took was "unreasonably dangerous under a consumer expectations test." *Freeman*, 618 N.W.2d at 840. The consumer expectations test requires that Plaintiff allege facts showing that Enbrel "was dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id*.

Defendants argue that Plaintiff's claim for design defect (Count I) should be dismissed for failure to plead the consumer expectations test. Plaintiff alleged that Enbrel contained an unreasonably dangerous defect in design or formulation; that an average consumer could not reasonably anticipate the dangerous nature of Enbrel or fully appreciate the risk of injury associated with using Enbrel; and that Enbrel presented a greater risk of injury than an ordinary consumer would expect when using this type of product. As facts supporting these allegations, Plaintiff alleged that Enbrel was sold as a medication to treat rheumatoid arthritis and that the side effects of Enbrel presented life-threatening conditions. Plaintiff specifically alleged that Decedent experienced complications from myelodysplastic syndrome and, as a direct result of

using Enbrel, he suffered injuries leading to death. These factual allegations, if true, allow for a reasonable inference that risk of death was a greater risk than an ordinary consumer would expect from consumption of medication for treatment of rheumatoid arthritis. Accordingly, the Court will not dismiss Plaintiff's claim for design defect.

IV. Plaintiff's Claims for Breach of Express Warranty and Negligence

Plaintiff's claims for relief based on breach of express warranty and negligence (Counts III and IV) do not set forth enough facts to make the claims facially plausible. *See Willmar Pub. Sch., Indep. Sch. Dist. No. 347*, 591 F.3d at 630 (quoting *Twombly*, 550 U.S. at 570) (internal quotation marks omitted). She has not pled "factual content that allows the court to draw the reasonable inference that the [Defendants are] liable for the misconduct alleged." *Ritchie*, 630 F.3d at 716 (quoting *Iqbal*, 556 U.S. at 678) (internal quotation marks omitted). Instead, she presents legal conclusions, which the Court is not required to accept.

Breach of Express Warranty

Under Neb. U.C.C. § 2-313, "in order to create an express warranty, the seller must make an affirmation of fact or promise to the buyer which relates to the goods and becomes part of the basis of the bargain. . . . [E]xpress warranties rest on 'dickered' aspects of the individual bargain." *Freeman*, 618 N.W.2d at 844.

In *Freeman*, the Nebraska Supreme Court dismissed a plaintiff's claim for breach of express warranty because "[t]he only allegation [the plaintiff] made regarding express warranty was that [the defendant] expressly warranted to her that Accutane was of marketable condition and that she relied on this warranty." *Id.* The plaintiff "did not allege any factual basis for this assertion." *Id.* The defendant "did not allege that any

such warranty was the basis of a bargain between herself and [the defendant]." *Id.* Accordingly, the court in *Freeman* found that, the plaintiff "did not allege a theory of recovery for breach of express warranty." *Id.*

Here, as in *Freeman*, Plaintiff only alleged that Defendants expressly warranted that Enbrel was of merchantable quality, fit, safe, and otherwise not injurious to the health of Decedent and capable of providing therapy to Decedent. Plaintiff did not allege any factual basis for this assertion. Nor did she allege that any such warranty was the basis of the bargain between Decedent and Defendants. Accordingly, Plaintiff's Claim for breach of express warranty will be dismissed with leave to amend.

Negligence

In order to state a claim for negligence under Nebraska law, a plaintiff must plead the elements of duty, breach, causation, and damages. *Jay*, 652 N.W.2d at 880. Defendants argue that Plaintiff's Complaint contains "no facts suggesting how the conduct of Defendant constituted a breach of duty . . . ." (Filing No. 11 at 19.)

An actor acts negligently or breaches a duty when "the [actor] does not exercise reasonable care under all the circumstances." *A.W. v. Lancaster Cnty. Sch. Dist. 0001*, 784 N.W.2d 907, 918 (Neb. 2010) (quoting Restatement (Third) § 3). "Primary factors to consider in ascertaining whether the person's conduct lacks reasonable care are the foreseeable likelihood that the person's conduct will result in harm, the foreseeable severity of any harm that may ensue, and the burden of precautions to eliminate or reduce the risk of harm." *Id.*

Plaintiff argues that the following factual allegations are sufficient to demonstrate breach: (1) Defendants failed "to exercise ordinary care in the design, formulation,

manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Enbrel" (Filing No.1 at ¶ 67), and (2) Defendants breached their continuing duty of pharmacovigilance. (*Id.* at ¶71). These allegations are no more than legal conclusions. Accordingly, Plaintiff's negligence claim will be dismissed with leave to amend.

V. Plaintiff's Loss of Consortium, Wrongful Death, and Survivor Action Claims

Defendants argue that Plaintiff's loss of consortium, wrongful death, and survivor action claims should be dismissed if the Court dismisses all of the underlying tort claims. The Court has not dismissed all of the underlying tort claims. Accordingly, these claims will not be dismissed at this time.

IT IS ORDERED:

1. Defendants' Motion to Dismiss (Filing No. 10) is granted in part as follows:
    a. To the extent Plaintiff's Strict Liability–Failure to Warn (Count II) and Negligent Failure to Warn (Count IV) claims allege fraud on the FDA and/or post-sale duties to warn, those claims are dismissed;
    b. To the extent Plaintiff's claim entitled "Fraud," Count VII, is a claim for fraud, such a claim is dismissed;
    c. To the extent Plaintiff's claim entitled "Fraud," Count VII, is a claim under the UDTPA and/or the NCPA, those claims are dismissed with leave to amend;
    d. Plaintiff's claim for breach of express warranty, Count III, is dismissed with leave to amend; and

e. Plaintiff's negligence claim, Count IV, is dismissed with leave to amend.

2. Defendants' Motion is otherwise denied; and

3. Plaintiff is given leave to file an Amended Complaint on or before October 14, 2014.

Dated this 29th day of September, 2014.

BY THE COURT:

s/Laurie Smith Camp
Chief United States District Judge